CAR
Writing Instruction
WI 318
Instruction for Writing and Analyzing Corrective Action Requests (CARs)
Major nonconformity:

A major nonconformity is one or more of:

a. the absence of, or total breakdown of, a system to meet a SAAS requirement. A number of minor nonconformities against one requirement can represent a total breakdown of the system and thus be considered a major nonconformity;

b. a nonconformity that judgment and experience indicate is likely either to result in the failure of the CB management system in meeting its goals and expectations or to materially reduce its ability to assure control of its policies and directives;

c. a nonconformity that poses an imminent threat.
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Minor nonconformity:

A minor nonconformity is a failure to comply with SAAS requirements which, based on judgment and experience, is not likely to result in the failure of the management system or reduce its ability to assure the ongoing viability and effectiveness of policies and procedures. It may be one of the following:

a. a failure or oversight in some part of the organization's management system which is not systemic in nature;

b. a single observed lapse in following one item of a company's management system;
How to categorize:

Collect and examine adequate objective evidence and determine what type of AR will be raised. This includes reviewing:

- an adequate sample size of records,
- number of occurrences within the system
- nonconformance existence in multiple functions and areas, and
- other indicators of a prevalent issue affecting the management system.
When are CARs raised:
- Document reviews: Cars are not raised – deficiencies are identified in doc review report
- Office – CARs may be raised and explained to CB when found before moving on to next topic
- Witness – related to:
  - planning process or related to audit procedures that are identified during the audit of the CB’s audit planning and preparation shall be reviewed with the CB auditor(s) at the time that they are found.
  - conduct of the audit, including validity of the CB auditor’s CARs, shall be communicated to the CB auditor at the time of the audit at the discretion of the SAAS auditor.

What does this mean?
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- CARs should be written so that they are addressed by the controlling office of the Certification Body.
- Each CAR issued shall contain sufficient but concise information to verify and substantiate the nonconformity identified during the audit.
- Each CAR must be understandable by the CB and SAAS staff.
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Summary:

An audit nonconformity (Corrective Action Request – CAR) finding shall have three distinct parts:

a. a statement of nonconformity,

b. the requirement, or specific reference to the requirement or normative element,

c. the objective evidence observed that supports the statement of nonconformity.
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Example:

- **Scenario:**

  An HQ office audit is being conducted and 7 audit packages have been selected for review. Three were initial audits, two were surveillance witness audits and two were surveillance office audits. Two of the stage 1 audits did not have an audit agenda in the packages and one surveillance office audit did not have an audit agenda.
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Using Form 415A:

- Details Of Nonconformity for CAR: There is no evidence that all SA8000 audits have audit plans
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- Guidelines for writing the Nonconformity for the CAR:
  - Use the wording from the requirement when possible
  - Do not include evidence in the wording of the nonconformity – state as a nonconformity to an identified requirement.
Guidelines for writing the Nonconformity for the CAR:

- Use the wording from the requirement when possible.
- Do not include evidence in the wording of the nonconformity – state as a nonconformity to a stated requirement.
- Use wording that supports the classification of the CAR – Major or Minor, for example:
  - Major – The management review process is not effectively implemented.
  - Major – There is no evidence that lead auditors are adequately qualified prior to conducting certification audits.
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Using Form 415A:

- Details Of Nonconformity for CAR: There is no evidence that all SA8000 audits have audit plans.
- Details Of Supporting Evidence for CAR: Seven audit packages were reviewed for (list seven audits reviewed including the name of the auditee and the date and type of audit conducted). Two of the three stage 1 audits did not have audit plans (identify client names) and one of two surveillance office audits (identify client name) did not have an audit plan.
Guidelines for recording the Supporting Evidence for a CAR:

- Each CAR issued shall contain sufficient but concise information to verify and substantiate the nonconformity identified during the audit, such as:
  - procedure numbers and references to records reviewed should be included, if applicable.
  - Sample size assessed,
  - number of persons interviewed,
  - observations made,
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Using Form 415A:

- Details Of Nonconformity for CAR: There is no evidence that all SA8000 audits have audit plans.
- Details Of Supporting Evidence for CAR: Seven audit packages were reviewed for (list seven audits reviewed including the name of the auditee and the date and type of audit conducted). Two of the three stage 1 audits did not have audit plans (identify client names) and one of two surveillance office audits (identify client name) did not have an audit plan.
- Text of Required Normative Element for CAR: The certification body shall ensure that an audit plan is established for each audit.
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Using Form 415A:

- Details Of Nonconformity for CAR: There is no evidence that all SA8000 audits have audit plans
- Details Of Supporting Evidence for CAR: Seven audit packages were reviewed for (list seven audits reviewed including the name of the auditee and the date and type of audit conducted). Two of the three stage 1 audits did not have audit plans (identify client names) and one of two surveillance office audits (identify client name) did not have an audit plan.
- Text of Required Normative Element for CAR: The certification body shall ensure that an audit plan is established for each audit
- Normative Document Reference: ISO 17021– 9.1.2
- CB Document Reference: SOP XXX
Guidelines for identifying the Normative Element for the CAR:

- CARs can be issued by grouping individual findings as long as they are against the same normative requirement. A CAR may only identify a nonconformity to a single requirement (Clause number).
- When more than one requirement may appear to be appropriate, the most appropriate requirement should be referenced. For example, a Procedure 200 requirement should be identified over a 17021 requirement if applicable.
- If the CB has a requirement within their SAMS certification process that is not being complied with, it should also be referenced.
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Examples:

- For the following, what would be the statement of nonconformity (if any) and what is the requirement not met? Also, are they minor or major?
  - During a witness audit, a SAAS auditor noted that the CB auditor did not react to conditions found during the facility tour that the SAAS auditor felt were nonconformities.
  - During a witness audit, a SAAS auditor noted that the CB auditor did not interview employees in a secure location.
  - During a managing office audit, there were no records of management reviews or internal audits available for the past two years.
  - During a managing office audit, the review of auditor records indicate that 4 of 9 auditors from three different regions do not meet minimum qualification requirements.
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CAR Numbering:

- The numbering scheme used to identify a CAR after initial accreditation shall identify the sequential number of CARs written against the CB since accreditation
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- **CAR Response Times:**
  - **Minor CAR**
    - Corrective Action Plan: 3 months
    - Corrective Action Complete: 6 months
  - **Major CAR**
    - Corrective Action Plan: 1 month
    - Corrective Action Complete: 3 months

SAAS must be notified as soon as possible by the auditor that a major CAR has been raised.

Normally, a major CAR should be verified by an on-site review at the HQ (managing) office at CA completion date (3 months)
Analysis of CAR responses:

- CB should utilize their internal corrective action process required by ISO 17021 clause 10.2 / ISO 9001– 8.5.2 or ISO 17021 clause 10.3.7 to manage corrective actions for SAAS CARs

- The CB shall respond to SAAS using the form 415B
  - All sections must be completed.
  - Major CAR responses should be analyzed for effectiveness on-site at the CB’s HQ office (special assessment).
  - Containment actions (Correction) should be included with corrective actions as appropriate

- SAAS shall not close the CAR unless there is evidence that the root cause has been effectively eliminated.
ANAB Heads Up, Issue 137 – Improved Corrective Action Responses may provide appropriate guidance as to when an accreditation auditor may close a CAR raised against a CB.
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HEADS UP

Issue: 137
Date: 2008/12/03
To: ANAB Applicant and Accredited CBs and Accreditation Assessors
From: Randy Dougherty, Vice President, ANAB
Re: Improved Corrective Action Responses

The ANAB process for CBs to respond to nonconformances involves several steps, including correction, root cause analysis, corrective action, evidence of implementation, and verification of effective implementation.
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NCR responses should be reviewed in three parts; correction, root cause analysis and corrective actions. These three parts are linked as outlined below.

11. In order to accept the plan it shall include;
   a. actions to address the root cause(s)
   b. Identification of responsible parties for the actions and
   c. a schedule (dates) for implementation.

12. In order to accept the evidence of implementation:
   a. Enough evidence is provided to show the plan is being implemented as outlined in the response (and on schedule).
   b. Note; Evidence in full is not required to close the NCR; some evidence may be reviewed during future assessment when verifying the corrective actions.
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That’s it folks!

Any questions?